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No. 06-1498

IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC
and PFIZER INC.,
Petitioners,
v.

KIMBERLY KENT, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

1. Whether, under the conflict preemption principles in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), federal law preempts state law to the extent that it requires the fact-finder to determine whether the defendant committed fraud on a federal agency that impacted the agency's product approval, where the agency – which is authorized by Congress to investigate and determine fraud – has not found any such fraud, and thus – as in *Buckman* – the state requirement would interfere with the agency's critical functions.

2. Whether, under the conflict preemption principles in *Buckman*, federal law preempts the provision in a Michigan statute that allows a product liability claim to be maintained against the manufacturer of an FDA-approved drug where, without an FDA finding of fraud on the agency, the fact-finder is required to make a finding under state law as to whether the manufacturer committed fraud-on-the-FDA and whether, in the absence of that fraud, the FDA would not have approved the drug.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke*, 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as the Federal Food, Drug, and Cosmetic Act (FDCA) at issue here.

WLF also believes that medical consumers are best served by the widest possible dissemination of truthful information about FDA-approved products, even when that truthful information relates to off-label uses of the product. WLF successfully challenged, on First Amendment grounds, Food and Drug Administration (FDA) efforts to suppress dissemination of such information. *Washington Legal Found. v. Friedman*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF is concerned that if suits such as Respondents' are determined not to be preempted by federal law, manufacturers will be reluctant to employ methods permissible under federal law for disseminating such information, or even to seek FDA approval for drugs with potentially beneficial off-label uses.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing due solely to its interest in the important preemption issues raised by this case. WLF is filing this brief with the consent of all parties. The written consents have been lodged with the Clerk of the Court.

STATEMENT OF THE CASE

This case involves state-law personal injury suits filed by Respondents, several Michigan residents who claim to have suffered injury after having taken Rezulin, a prescription drug approved by FDA for treatment of diabetes. The suits were initially filed in state court in Michigan, were removed to federal district court by the defendants, and then were transferred to the U.S. District Court for the Southern District of New York pursuant to 28 U.S.C. § 1407 in connection with multidistrict litigation proceedings.

At issue is whether the federal law of preemption applies to a portion of a Michigan statute that the parties agree is applicable to the claims here. In 1995, Michigan adopted MCL § 600.2946(5), a statute that provides a prescription drug manufacturer or seller with "an *absolute defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Taylor v. SmithKline Beecham Corp.*, 468 Mich. 1, 7 (2003) (emphasis added). The statute provides exceptions to that "absolute defense" in two limited situations: (a) if the defendant "intentionally withholds from or misrepresents to" FDA information concerning the drug that is required by federal law to be submitted to FDA *and*, had the information been accurately submitted, FDA would not have approved the drug or would have withdrawn approval; or (b) if the defendant "makes an illegal payment" to an FDA official for the purpose of securing or maintaining approval of the drug. MCL § 600.2946(5)(a) & (b).[2]

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[2] Respondents concede both that Rezulin was FDA-approved at all relevant times and that the drugs they took (and their labeling) were in compliance with FDA's approval at the time the drugs left the control

(continued...)

Petitioners Warner-Lambert Company LLC and Pfizer Inc. (hereinafter, collectively "Warner-Lambert") moved in the district court for judgment on the pleadings, contending that because Rezulin was an FDA-approved product, Respondents' claims were barred by MCL § 600.2946(5). Warner-Lambert asserted that Respondents could not seek to lift that bar by relying on the statute's fraud-on-the-FDA exception because that exception was preempted by federal law. The district court agreed, basing its preemption holding on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2000), and *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). Pet. App. 29a-38a.

The Second Circuit reversed. *Id.* 1a-28a. While recognizing that its decision directly conflicted with the Sixth Circuit's *Garcia* decision, the Second Circuit held that MCL § 600.2946(5)'s fraud-on-the-FDA exception was not preempted by federal law. The appeals court said that the Michigan statutory exception "d[id] not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*," which the appeals court identified as the "impos[ition of] significant and distinctive burdens on the FDA and the entities it regulates." *Id.* 27a. The court also distinguished *Buckman* on the grounds that while *Buckman* had determined that "the presumption against preemption of a state law cause of action" did not apply in that case, *id.* 16a, the

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[2](...continued)
of Petitioners. Given that concession, it is of little moment – for purposes of determining the preemption issue raised herein – whether (as the Second Circuit contended, Pet. App. 23a-24a) the existence of FDA approval should be deemed an "affirmative defense," or whether the absence of FDA approval is a necessary element of Respondents' cause of action. Under either scenario, the bar against Petitioners' liability herein is "absolute" under Michigan law unless Respondents can come forward with evidence demonstrating fraud on the FDA.

presumption *did* apply to Respondents' claims because those claims sought to impose "traditional" common law liability and were not "an attempt to police fraud against the FDA." *Id.* 18a-19a. The appeals court said that a preemption finding would be tantamount to a holding that Congress had intended to "gut[] traditional state law duties between pharmaceutical companies and their consumers." *Id.* 20a. The court said that it was unwilling to ascribe such intent to Congress "[u]ntil and unless Congress states *explicitly* that it intends invalidation of state common law claims." *Id.* 24a (emphasis added).

Following the Second Circuit's denial of panel rehearing and rehearing *en banc*, *id.* 39a-40a, Warner-Lambert sought review in this Court.

REASONS FOR GRANTING THE PETITION

This case presents an issue of exceptional importance to pharmaceutical companies as well as to health care consumers throughout the country: is it an appropriate function of courts hearing state-law causes of action to impose liability based on their determinations regarding whether a pharmaceutical company defrauded the FDA for the purpose of obtaining FDA approval to market its product? This Court held in *Buckman* that state-law fraud-on-the-FDA claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives" and also "dramatically increase the burdens" facing companies applying for approval to market new drugs – and thus that Congress had impliedly preempted such claims when it established FDA's regulatory authority by enacting the FDCA. The issue here is whether those very same conflicts are an insufficient basis to find implied preemption when the state court second-guesses an FDA drug-approval decision not (as in *Buckman*) in connection with a fraud-on-the-FDA claim, but rather for the purpose of

determining a plaintiffs' entitlement to an exception from a state-created "absolute" bar to tort liability.

Review is warranted because the issues raised are of profound importance to health care in this country. The issues affect product liability litigation not only in Michigan but also in the many other States that have adopted tort reform laws similar to Michigan's in that they contain fraud-on-the-FDA exceptions to broad-based limitations on liability. If those exceptions are not deemed preempted, courts across the nation will be second-guessing FDA determinations that a drug is sufficiently safe and effective for its intended uses. That process will in turn create all the difficulties identified in *Buckman* as the basis for this Court's determination that fraud-on-the-FDA lawsuits are impliedly preempted by federal law – including, for example, a "skew[ing]" of the "somewhat delicate balance of statutory objectives" that FDA seeks to maintain. *Buckman*, 531 U.S. at 348. That process could also have a significant impact on the development of new, life-saving therapies. Review is warranted to determine whether Congress really intended to permit such impacts on the regulatory scheme it adopted. Moreover, so long as the issue remains unsettled, States interested in adopting tort reform legislation – and there is considerable evidence that many States have adopted, or are considering adopting, reform legislation designed to ensure that high litigation costs do not deter pharmaceutical companies from developing new, lifesaving therapies – will remain confused regarding how to do so in a manner that does not conflict with federal law.

Review is also warranted because the decision below directly and irreconcilably conflicts with the Sixth Circuit's decision in *Garcia*. Indeed, the Second Circuit made no effort to play down its fundamental disagreement with the Sixth Circuit on the scope of federal preemption. *See, e.g.*, Pet. App.

18a ("We disagree" with the Sixth Circuit's conclusion that there is "no meaningful difference" between *Buckman* and the preemption issue raised herein.) Although *Garcia* arose in a slightly different context – it was the *plaintiff* in *Garcia* who was arguing the most strenuously that Michigan's fraud-on-the-FDA exception was preempted by federal law – the precise issue raised by this Petition was decided in *Garcia* in a manner that is diametrically opposed to the decision below.

Review is also warranted because the decision below is so clearly at odds with *Buckman* and other decisions of this Court that have addressed federal preemption claims. The Second Circuit held that when a state-law tort action is designed to enforce the historic police powers of the State, Congress should *never* be deemed to have intended to preempt the action based solely on concerns that the court would be required to examine fraud-on-the-FDA issues, unless Congress has expressed that intent "explicitly." Pet. App. 24a. In so holding, the Second Circuit wrote off much of the doctrine of implied preemption in a manner that conflicts with numerous decisions of this Court.

Moreover, the Second Circuit badly misconstrued the presumption against preemption. The ultimate touchstone of preemption analysis is congressional intent; the "presumption against preemption" is merely an interpretive guide designed to assist the courts in discerning that intent. *Buckman* held that state-law fraud-on-the-FDA suits were impliedly preempted after identifying numerous ways in which judicial re-examination of fraud-on-the-FDA issues would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Once such "stand as an obstacle" findings have been made, a preemption determination is clearly mandated, and there is no need to resort to tie-breaking presumptions. The "presumption against preemption" cannot legitimately be invoked as a basis for ignoring this

Court's determination in *Buckman* that Congress's purposes and objectives would be frustrated by allowing the types of judicial inquiries that litigating MCL § 600.2946(5)'s fraud-on-the-FDA exception would entail.

I. REVIEW IS WARRANTED BECAUSE THE ISSUE AFFECTS TORT REFORM LAWS IN NUMEROUS STATES

Review is warranted because the issues raised are of profound importance to health care in this country. In recognition of the negative impact that excessive tort liability can have on the development of new, life-saving therapies, numerous States have adopted reform laws (such as the Michigan statute at issue here) designed to impose reasonable limits on such tort suits; many of the laws include fraud-on-the-FDA exceptions similar to the exception contained in MCL § 600.2946(5). Resolution of the issues raised herein will also resolve whether the fraud-on-the-FDA exceptions contained in those other state laws are similarly preempted.

Texas has adopted a statute that creates a rebuttable presumption of pharmaceutical company non-liability in product liability actions if the drug in question is labeled in compliance with FDA requirements. TEX. CIV. PRAC. & REM. CODE § 82.007(a). The presumption is inapplicable if the plaintiffs can demonstrate that the defendant obtained FDA approval for its drug by means of fraud on the FDA. *Id.*, § 82.007(b)(1). New Jersey has adopted a similar statute creating a rebuttable presumption that the warning on a drug or medical device is adequate if the warning was approved or prescribed by FDA. N.J. STAT. ANN. § 2A:58C-4. New Jersey goes further and prohibits an award of punitive damages in a case involving an approved drug or device, so long as the plaintiffs cannot

demonstrate that the defendant defrauded the FDA in order to win approval. N.J. STAT. ANN. § 2A:58C-5.

Five States have adopted limitations on punitive damages similar to New Jersey's. Each of those statutes includes an exception in cases in which plaintiffs can demonstrate that the drug company obtained product approval by defrauding FDA. *See* ARIZ. REV. STAT. § 12-701; N.D. CENT. CODE § 32-03.2-11(6), (7)(a); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. § 30.927; UTAH CODE ANN. § 78-18-2. A decision in this case would determine the validity of the fraud-on-the-FDA exceptions contained in each of these seven statutes. As the Petition makes clear (Pet. 12-13 & n.7), whether the various fraud-on-the-FDA exceptions contained in these tort reform statutes are preempted by federal law is a frequently litigated issue, and courts have reached divergent results. Review is warranted to provide guidance to courts hearing preemption challenges to these fraud-on-the-FDA exceptions.

More broadly, health care experts throughout the country have increasingly come to recognize that health care suffers when product liability suits against pharmaceutical manufacturers proliferate too freely. As just one example, it is widely acknowledged that the on-going nationwide shortage of vaccines is in significant part attributable to vaccine manufacturers being driven from the market by high litigation costs. *See, e.g.*, General Accounting Office, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges* (Sept. 2002) (recent childhood vaccine shortages are at least partially attributable to liability concerns and litigation defense cost). The federal government has sought to ameliorate this litigation-driven problem by enacting legislation – the National Childhood Vaccine Act, 42 U.S.C. § 300aa-1 *et seq.* – protecting vaccine manufacturers from some of the costs of product liability litigation.

As the state statutes cited above indicate, numerous States are similarly interested in providing an appropriate balance between (on the one hand) protecting their citizens from injuries caused by the unreasonable conduct of product manufacturers and (on the other hand) protecting public health by ensuring that high litigation costs do not deter pharmaceutical manufacturers from continuing to develop and market new, lifesaving therapies.[3] Those States need guidance from the Court regarding how best to maintain that balance. Many States have opted to deter unreasonable pharmaceutical manufacturer conduct by including fraud-on-the-FDA exceptions in their tort reform legislation; review of this case is warranted to provide guidance from the Court regarding whether federal law permits adoption of such provisions.

II. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH OTHER FEDERAL APPELLATE DECISIONS

Review is also warranted because the decision below directly and irreconcilably conflicts with other federal appellate decisions, particularly the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004). The Sixth

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[3] The business community is less willing to continue to spend the huge sums necessary to bring new pharmaceutical products to market in the face of an increasingly hostile litigation climate. Recent studies have concluded that the average cost of bringing new pharmaceutical products to market is as high as $1.7 billion. *See* Pharmacy Times, "Drug Development" (Dec. 2005) (available at http://www.pharmacytimes.com/Article.cfm?Menu=1&ID=2865). Tufts University pegs the average cost of developing a new biotechnology product at $1.2 billion. Tufts Center for the Study of Drug Development, *Average Cost to Develop a New Biotechnology Product Is $1.2 Billion* (Nov. 9, 2006) (available at http://csdd.tufts.edu/NewsEvents/NewsArticle. asp?newsid=69).

Circuit held that Michigan's fraud-on-the-FDA exception to drug manufacturer immunity is preempted by federal law; disagreeing, the Second Circuit held that state-law tort claims invoking that exception are *not* preempted. Nor can the Second Circuit's rationale be squared with the approach that other federal appeals courts have adopted in cases raising preemption issues. Review is warranted to resolve this conflict on an important and recurring issue of federal law.

Indeed, the Second Circuit could not have been clearer in expressing its disagreements both with *Garcia*'s holding and its major premises. For example, the Second Circuit stated explicitly, "We disagree," in response to the Sixth Circuit's assertion that there is "no meaningful difference" between *Buckman* and the preemption issue raised herein. Pet. App. 18a.

Garcia arose in a somewhat different factual context, but that difference does not diminish the irreconcilable nature of the conflict between the Second and Sixth Circuits on the questions presented herein. In *Garcia*, the plaintiff sought invalidation of MCL § 600.2946(5) in its entirety. The Sixth Circuit agreed with the plaintiff that *Buckman* required a finding that Michigan's fraud-on-the-FDA exception was preempted – at least where (as was true in that case) FDA had not itself concluded that it had been defrauded. *Garcia*, 385 F.3d at 966. But the Sixth Circuit rejected the plaintiff's argument that the preemption finding required invalidation of the entire statute. Rather, citing Michigan's general severability clause,[4] the Sixth Circuit held that the remainder of MCL § 600.2946(5) (*i.e.*,

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[4] MCL § 8.5 ("If any portion of an act or the application thereof to any person or circumstance shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application . . ., and to this end acts are declared to be severable.").

those portions remaining following excision of the exceptions set forth in (a) and (b)) should continue in force. *Id.* at 967. The court said, "Given a choice between immunity absent a finding of bribery or fraud by the Federal Government and no immunity, the Michigan Legislature would prefer the former option." *Id.*

In other words, although the Sixth Circuit was not faced with a claim that the defendant manufacturer had defrauded the FDA,[5] the legal issue it decided was the precise issue decided by the Second Circuit in this case, and the two appeals courts decided the issue in an irreconcilably conflicting manner.

Moreover, this case provides a particularly good vehicle for addressing the conflict, because the preemption issue is the *only* issue on which the two appeals courts disagreed. In particular, hearing this case would not require the Court to focus on issues peculiar to Michigan law, because the Second Circuit did not disagree with the Sixth Circuit's severability analysis. To the contrary, the Second Circuit made clear that it deemed itself bound to follow the Sixth Circuit's interpretation of Michigan law, in light of Michigan's location within the Sixth Circuit. Pet. App. 10a (citing *Factors Etc., Inc. v. Pro Arts, Inc.*, 625 F.2d 278, 279 (2d Cir. 1981)).[6] Accordingly, had the

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[5] In granting summary judgment, the district court had held that the plaintiff failed to submit evidence supporting her fraud-on-the-FDA claim, and the plaintiff did not appeal from that holding. *Id.* at 964 n.1.

[6] A Michigan state appellate court recently adopted *Garcia*'s preemption analysis as well as its severability analysis regarding the remainder of MCL § 600.2946(5). *Duronio v. Merck & Co.*, 2006 Mich. App. LEXIS 1841, *17 (Mich. App. June 13, 2006) ("Although we are not bound to follow the decision in *Garcia*, . . . we agree with its holding that [MCL § 600.2946(5)'s] fraud-on-the-FDA exception is

(continued...)

Second Circuit adopted Garcia's preemption analysis, one can confidently predict that the court would have upheld the district court's dismissal of all claims against Warner-Lambert.

As the Petition explains in detail, the Second Circuit's preemption analysis also conflicts with the analysis adopted by the Third and Ninth Circuits. Pet. 8-9. The Second Circuit held that *Buckman* does not require preemption of a state-law cause of action unless a claim of fraud-on-the-FDA is the *sole* basis of the cause of action. Pet. App. 19a-23a. In contrast, the Third and Ninth Circuits have adopted an analytic approach akin to the Sixth Circuit's in *Garcia*: a state-law cause of action is preempted any time the plaintiff, in order to prevail, is required to demonstrate that a federal agency has been defrauded, and the resultant inquiry would require the state courts and juries to second-guess the agency's decision-making. *See Nathan Kimmel, Inc. v. DowElanco,* 275 F.3d 1199, 1205-06 (9th Cir. 2001); *Michael v. Shiley*, 46 F.3d 1316, 1329 (3d Cir. 1995).

An inevitable consequence of allowing the conflict between the Second and Sixth Circuits to persist would be a significant increase in forum shopping among Michigan residents seeking to assert product liability claims against manufacturers of FDA-approved products. Any such manufacturer that does business within the states comprising the Second Circuit (and virtually every large pharmaceutical or medical device company does so) will likely discover that *all* product liability claims filed against them by Michigan residents are filed in Connecticut, New York, or Vermont. In many cases, the plaintiffs' choice of a forum outside their native Michigan will be outcome determinative regarding whether their claims

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[6](...continued)
preempted by federal law unless the FDA itself determines that it was defrauded.").

are barred by Michigan's tort reform statute. The significant potential for such forum shopping provides an additional reason for granting review.

The importance of the conflict between the circuits is heightened in light of the frequent resort to Multidistrict Litigation (MDL) proceedings in federal-court product liability actions involving FDA-approved products. Respondents' claims, for example, were transferred by the Judicial Panel on Multidistrict Litigation from federal court in Michigan to the Rezulin MDL in the U.S. District Court for the Southern District of New York. Federal law requires that such a claim be remanded "at or before the conclusion of . . . pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated." 28 U.S.C. § 1407(a).[7] Thus, it is virtually certain that these claims will eventually return to Michigan federal district courts, which are, of course, bound by Sixth Circuit decisions. Any such return would almost surely reignite the dispute between the parties regarding preemption – federal law is unsettled regarding whether transferor courts must, after a remand, follow the law of the case established by the consolidation court or, conversely, follow the clearly established law of the circuit within which they sit.

Indeed, then-Judge Ruth Bader Ginsberg faced precisely this dilemma in an appeal from MDL proceedings conducted by the U.S. District Court for the District of Columbia. She authored a decision for the D.C. Circuit that decided airline damage-limitations issues in a manner that conflicted with a prior Second Circuit decision. *In re Korean Air Lines Disaster*, 829 F.2d 1171, 1173-76 (D.C. Cir. 1987), *aff'd* 490 U.S. 122

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[7] This Court has held that remand of a non-terminated case following completion of pretrial proceedings is *mandatory*. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

(1989). But the D.C. Circuit recognized that some of the consolidated cases would eventually be returned to courts within the Second Circuit, and conceded that "our circuit is not positioned to speak the last word" on whether those transferor courts would apply the D.C. Circuit rule or the conflicting Second Circuit rule. *Id.* at 1176. That conundrum was avoided only because this Court ultimately granted review and adopted the D.C. Circuit's position. *Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989). Unless the Court similarly grants the Petition in this case and resolves the conflict between the Second and Sixth Circuits, it may eventually be faced with the spectacle of two federal appeals court issuing conflicting decisions *in the very same case.*[8]

III. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH *BUCKMAN* AND THIS COURT'S OTHER PREEMPTION DECISIONS

Review is also warranted because the decision below is so clearly at odds with *Buckman* and other decisions of this Court that have addressed federal preemption claims.

Buckman involved state-law claims that a medical device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. The plaintiffs contended that FDA would not have approved the

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[8] At least one federal appeals court – the Eleventh Circuit – has stated its unwillingness to apply law of the case doctrine in a case transferred to a district court within the circuit, when doing so would require it to ignore its own binding precedent. *Murphy v. F.D.I.C.*, 208 F.3d 959, 967 (11th Cir. 2000) (refusing to abide by a pre-transfer D.C. Circuit decision, the court explained, "we are not, therefore, bound by the 'law of the case' doctrine to adhere to a ruling with which we have emphatically and repeatedly disagreed").

device (and thus they never would have been injured by the product) but for the fraud. The Court unanimously held that Congress had impliedly intended to preempt such state-law fraud-on-the-FDA claims when it adopted the FDCA, because adjudication of such claims would conflict with the FDA product-approval process. *Buckman*, 531 U.S. at 348. The Court identified numerous ways in which judicial re-examination of fraud-on-the-FDA issues would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, including that it would: (1) conflict with FDA's responsibility to address fraud allegations in a flexible manner, so as not to interfere (for example) with the right of physicians to prescribe FDA-approved products for uses not approved by FDA; (2) discourage manufacturers from seeking approval of medical products with potentially beneficial off-label uses; and (3) cause applicants seeking product approval to submit a deluge of information to FDA that it neither wants nor needs, thereby delaying approval of new products. *Id.* at 349-51.[9]

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[9] In its *amicus* brief urging the Court to hold that fraud-on-the-FDA causes of action are preempted, the United States highlighted yet another practical concern: permitting such suits to go forward will lead to numerous demands to depose FDA officials. The United States asserted:

> [W]idespread litigation could be expected on whether testimony and other evidence could be secured from FDA. . . . The prospect of such intrusive inquiries and attendant litigation would pose a significant potential for diverting FDA's resources from the important health mission that Congress has assigned to it and for distorting FDA's internal decisionmaking process.

Buckman Co. v. Plaintiffs' Legal Comm., No. 98-1768 (Brief for the United States as *Amicus Curiae* Supporting Petitioner) at 29 (Sept.

(continued...)

The Second Circuit did not dispute that permitting courts to examine whether FDA has been defrauded raises the concerns identified in *Buckman*, regardless whether that examination occurs in connection with a state-law fraud-on-the-FDA cause of action or in connection with determining the applicability of Michigan's fraud-on-the-FDA exception to the bar on drug manufacturer liability. *Buckman* held that the concerns it identified demonstrated that Congress had impliedly preempted fraud-on-the-FDA causes of action, because such judicial inquiries stood as an obstacle to the accomplishment of Congress's objectives.[10] The Second Circuit nonetheless held that the presumption against preemption of state-law tort actions raising traditional common law claims served to distinguish this case from *Buckman*. Pet. App. 18a-24a.

The Second Circuit badly misconstrued the presumption against preemption. Any such presumption is merely a tool to assist in deciding the ultimate issue in a preemption case: did Congress intend to prevent State and local governments from exercising authority over an issue of concern to the federal government?[11] As the Court has repeatedly emphasized, "Preemption fundamentally is a question of congressional intent." *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990).

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[9](...continued)
2000).

[10] Implied conflict preemption is said to occur "when a state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

[11] It is beyond dispute that when Congress chooses to preempt State and local regulation of commerce, it is entitled to do so under the Supremacy Clause. U.S. Const., art. VI, cl. 2.

Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) ("'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis") (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486-87 (1996) ("any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose.*'") (emphasis in original) (quoting *Cipollone*, 505 U.S. at 530 n.27 (opinion of Stevens, J.)).

When Congress's purpose is obscure, the presumption against preemption is a rule of construction that helps reveal that purpose. But thanks to *Buckman*, we *already know* what Congress intended: Congress sought to prevent States from second-guessing FDA product-approval decisions in a manner that causes the types of administrative difficulties described in *Buckman*, because Congress believed that such activities would stand as an obstacle to the accomplishment of FDA's objectives. Because the administrative difficulties identified in *Buckman* also arise when a court undertakes to determine whether MCL § 600.2946(5)'s fraud-on-the-FDA exception applies, we already know from *Buckman* that Congress intended to preempt such judicial inquiries. Under those circumstances, there is no need to resort to tie-breaking presumptions to discern congressional intent. The Second Circuit erred in applying the presumption against preemption as its basis for discerning a congressional purpose wholly at odds with the purpose discerned in *Buckman*.

The Second Circuit apparently based its ruling on a concern that a preemption finding would be tantamount to holding that Congress had intended to "gut[] traditional state law duties between pharmaceutical companies and their consumers." Pet. App. 20a. That concern was not well-founded. It is the Michigan legislature, not Congress, that determined – when it adopted MCL § 600.2946(5) – that a

major restructuring of traditional state law duties was appropriate, in order to ensure that excessive product liability litigation did not undermine effective health care. Regardless how the Court rules on this preemption issue, the Michigan legislature will be free to restore traditional common law duties any time it deems appropriate.

In finding against preemption, the Second Circuit relied on this Court's decision in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), which rejected a claim that federal regulation of nuclear power preempted a common law suit against a nuclear power plant operator. That reliance was misplaced. As *Buckman* explained, the *Silkwood* decision "turned on specific statutory evidence that Congress 'disclaimed any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials.'" *Buckman*, 531 U.S. at 352 (quoting *Silkwood*, 464 U.S. at 257). There is no similar statutory evidence here; to the contrary, as the Petition explains in detail, all the statutory evidence indicates that (as *Buckman* held) Congress intended to preempt all common law causes of action that require second-guessing of FDA product-approval determinations.

Finally, the Second Circuit – in conflict with numerous decisions of this Court – essentially wrote off much of the doctrine of implied preemption. The court held that when a state-law tort action is designed to enforce the historic police powers of the State, Congress should *never* be deemed to have intended to preempt the action based solely on concerns that the court would be required to examine fraud-on-the-FDA issues, unless Congress has expressed that intent "explicitly." Pet. App. 24a. This Court repeatedly has made clear that Congress can be deemed to have intended to preempt state law even when it has not said so explicitly. If Congress's express language

does not directly answer the preemption question at issue, "courts must consider whether the federal statute's 'structure and purpose,' or nonspecific statutory language nonetheless reveal a clear, but implicit, preemptive intent." *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 20 (1996) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Review is warranted because the Second Circuit's decision is so badly out of step with this Court's preemption case law.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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